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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,649	01/14/2002	Richard A. Young	2869.1001-023	3487

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BOSTON, MA 02110

EXAMINER

BROWN, STACY S

ART UNIT	PAPER NUMBER
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1648

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DATE MAILED: 05/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/046,649	YOUNG ET AL.	
	Examiner	Art Unit	
	Stacy S Brown	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1648

DETAILED ACTION

1. Applicant's preliminary amendments filed January 14, 2002 and October 22, 2002 are acknowledged and entered. Claim 13 is pending and examined.

Priority

2. This application claims priority back to USSN 07/207,298 filed June 15, 1988, now abandoned. Upon review of the disclosures of the applications relating to the instant application, it has been determined that the disclosure of the application USSN 08/073,381, filed June 4, 1993, is the earliest filed application that supports the subject matter of claim 13. The application USSN 07/804,632 filed December 9, 1991, does not disclose hsp-antigen complexes. Therefore, the claimed subject matter is entitled to the priority of the filing date of the application USSN 08/073,381, filed June 4, 1993.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 13, "for use in inducing an immune response" is unclear because the claim is drawn to a vaccine. A vaccine is used to prevent or protect against infection. Clarification is required regarding the purpose of the vaccine in the preamble and the conclusion of the claim.

Art Unit: 1648

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunogenic composition that induces an immune response against a substance, does not reasonably provide enablement for a vaccine that protects against a substance. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The breadth of the claims is unreasonable, encompassing protection against any substance against which an immune response is desired such as viruses, bacteria, fungi, protozoa, autoimmune disease, etc. The nature of the invention is drawn to a vaccine that protects against infection by administering a composition comprising a heat shock protein fused to an antigen. The state of the art regarding protective vaccines against viruses such as HIV shows unpredictability. Walker *et al* (*Nature* 407:313-314, 2000) says that single amino-acid changes in an HIV peptide can prevent the peptide from being presented to CTLs. Barouch *et al* (*Nature* 415:335-339, 2002) supports Walker by showing a single nucleotide mutation within an immunodominant Gag CTL epitope that caused an increase in viral replication, leading to a test animal's death (abstract). Barouch demonstrates that protective antigens for HIV are unpredictable. Applicant has not provided guidance for overcoming the unpredictability of preventing HIV, nor shown working examples. Although the prior art shows that antigens fused

Art Unit: 1648

to heat shock proteins elicit strong immune responses, there is no support for their ability to prevent infection. Therefore, given the breadth of the claims, the state of the art, the high degree of unpredictability and the lack of working examples, it would require undue experimentation to make or use the heat shock protein/peptide fusion to protect against all types of infections.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Cox (*Eur. J. Immunol.*, 1988) or Engel (*Biomed. Biochim. Acta*, 1991). The claim is drawn to a vaccine comprising a recombinant fusion protein that induces an immune response. The Office has based this rejection on the interpretation that the claim is drawn to an immunogenic composition, not a vaccine. The fusion protein includes a stress protein or portion thereof fused to a substance or portion thereof against which an immune response is desired.

Cox teaches a fusion protein comprising part of a stress protein linked by a peptide bond to a heterologous peptide, administration of the fusion to an animal and an improved immune response induced by the fusion (abstract). Therefore, Cox anticipates the claim.

Engel teaches a fusion protein comprising parts of a mouse and human stress protein; the human protein is identified as a tumor-associated protein. The fusion protein is administered to a

Art Unit: 1648

nonhuman animal, and an improved immune response is induced (abstract). Therefore, Engel anticipates the claim.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 13 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-52 of U.S. Patent No. 6,338,952 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent are a species of the genus claimed in the instant claim 13. The instant claim

Art Unit: 1648

is drawn to a vaccine comprising a recombinant fusion protein. The claims of the patent are drawn to an isolated fusion protein or composition comprising the isolated fusion protein.

Conclusion

7. No claim is allowed.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy S. Brown, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday from 6:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SSB

Stacy S. Brown
May 1, 2003


JAMES HOUSEL 5/4/03
SUPERVISORY PATENT EXAMINER
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